

SAFETY DATA SHEET

1. Identification

Product identifier Alprazolam CIV

Other means of identification

 Catalog number
 1015008

 CAS number
 28981-97-7

Chemical name 4H-[1,2,4]Triazolo[4,3-alpha][1,4]benzodiazepine, 8-chloro-1-methyl-6-phenyl-

Recommended use Specified quality tests and assay use only.

Recommended restrictionsNot for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company nameU. S. PharmacopeiaAddress12601 Twinbrook Parkway

Rockville MD 20852-1790 United States

Telephone RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 4

Serious eye damage/eye irritation Category 2B Reproductive toxicity Category 2

Specific target organ toxicity, single exposure Category 3 narcotic effects

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Harmful if swallowed. Causes eye irritation. May cause drowsiness or dizziness. Suspected of

damaging fertility or the unborn child.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Wear protective gloves/protective clothing/eye protection/face protection. Wash thoroughly after handling. Avoid breathing dust/fume/gas/mist/vapors/spray. Use only outdoors or

in a well-ventilated area.

Response If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove

person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If

exposed or concerned: Get medical advice/attention.

Storage Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Potent pharmacologically active material.

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3. Composition/information on ingredients

Substance

Ingestion

Chemical name	Common name and synonyms	CAS number	%	
Alprazolam CIV		28981-97-7	100	

4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

Call a physician if symptoms develop or persist.

Rinse skin with water/shower. Get medical attention if irritation develops and persists. Skin contact

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if

present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

Get medical advice/attention if you feel unwell.

Most important symptoms/effects, acute and

delayed

Indication of immediate medical attention and special

treatment needed

Narcotic effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Provide general supportive measures and treat symptomatically. Treatment of benzodiazepine overdose may include the following: Do NOT Induce vomiting. Administer activated charcoal as a slurry. If patient is unconscious, perform gastric lavage with cuffed endotracheal tube. Monitor respiration, pulse, and blood pressure, and maintain an adequate airway. Give intravenous fluids to control blood pressure. After airway, ventilation, and intravenous access have been secured, administer flumazenil, a specific benzodiazepine receptor antagonist, to reverse sedative effects. Do NOT use barbiturates to control excitation.

General information Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must

receive immediate medical attention.

5. Fire-fighting measures

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding Suitable extinguishing media

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment

and precautions for firefighters

Wear suitable protective equipment.

Fire fighting equipment/instructions

Specific methods

General fire hazards

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Material name: Alprazolam CIV USP SDS US

8. Exposure controls/personal protection

Occupational exposure limits

Exposure limit values

Industrial Use

Material Value **Type** 0.25 Alprazolam CIV (CAS **TWA** micrograms/m3 28981-97-7)

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Eye/face protection

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Hand protection Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When

the material is dissolved or suspended in an organic solvent, wear gloves that provide protection

against the solvent.

Other Train employees in proper gowning and degowning practices. Wear disposable lab coat,

> disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head Respiratory protection

cover for spill cleanup. Chose respiratory protection appropriate to the task and the level of

existing engineering controls.

Wear appropriate thermal protective clothing, when necessary. Thermal hazards

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or

quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.

Form Crystalline powder. Color White. Off-white. Odor Not available **Odor threshold** Not available. Not available. pН

442.4 - 443.3 °F (228 - 228.5 °C) Melting point/freezing point

Initial boiling point and boiling

range

Not available.

Flash point Not available. Not available. **Evaporation rate** Not available. Flammability (solid, gas) Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Not available.

Flammability limit - upper

Not available. Explosive limit - lower (%) Explosive limit - upper (%) Not available

< 0.0000001 kPa at 25 °C Vapor pressure

Not available. Vapor density Not available Relative density

Solubility(ies)

Solubility (water) Insoluble.

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Chloroform: Freely soluble Solubility (other)

Ethanol: Soluble

Acetone: Sparingly soluble Ethyl acetate: Slightly soluble

Partition coefficient

(n-octanol/water)

2 12

Not available. **Auto-ignition temperature** Not available. **Decomposition temperature** Not available. **Viscosity**

Other information

Chemical family Benzodiazepine. Molecular formula C17-H13-CI-N4 Molecular weight 308.77 g/mol

10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Contact with incompatible materials. Conditions to avoid

Incompatible materials Strong bases. Mineral acids Strong oxidizing agents.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. Cl-.

11. Toxicological information

Information on likely routes of exposure

Inhalation Knowledge about health hazard is incomplete. Skin contact Knowledge about health hazard is incomplete.

Causes eve irritation. Eye contact

Harmful if swallowed. Based on information from therapeutic use, this material may cause: Ingestion

Narcotic effects.

Symptoms related to the

physical, chemical, and

toxicological characteristics Benzodiazepines: Headache. Weakness. Unsteadiness. Drowsiness. Dizziness. Fast or slow heartbeat. Difficulty breathing. Blurred or double vision. Slurred speech. Memory loss. Confusion.

Hallucinations. Cold, clammy skin. Gastrointestinal disturbances.

Information on toxicological effects

Harmful if swallowed. **Acute toxicity**

Product Species Test Results

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Acute Oral

LD50 Mouse 770 mg/kg Rat 1220 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye

irritation

Causes eye irritation.

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete. Skin sensitization Knowledge about health hazard is incomplete. Germ cell mutagenicity Knowledge about mutagenicity is incomplete. Knowledge about carcinogenicity is incomplete. Carcinogenicity

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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Reproductive toxicity

Suspected of damaging fertility or the unborn child. Most studies do not show a strong association

between maternal therapeutic use of benzodiazepines and malformations in the offspring, although the risk of malformations may be increased. Withdrawal effects have been observed in newborns

following maternal benzodiazepine use. Knowledge about health hazard is incomplete.

Specific target organ toxicity -

single exposure

Narcotic effects.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard Knowledge about health hazard is incomplete.

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause

physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability Bioaccumulative potential

No data is available on the degradability of this product.

Octanol/water partition coefficient log Kow

2.12

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Local disposal regulationsDispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to

Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulationsThis product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

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SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

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SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

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Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

Drug Enforcement Schedule IV - 2882

Administration (DEA) (21 CFR

1308.11-15)

US state regulations

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Inventory name

Alprazolam CIV (CAS 28981-97-7) Listed: July 1, 1990

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd.

(a))

Alprazolam CIV (CAS 28981-97-7)

International Inventories

Country(s) or region

Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

^{*}A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 11-23-2009

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herein.

Material name: Alprazolam CIV USP SDS US

On inventory (yes/no)*